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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,898	08/22/2003	Joar Opheim	03-109	1343
23843	7590	07/31/2007		
FOOTHILL LAW GROUP 777 N. FIRST STREET, SUITE 325 SAN JOSE, CA 95112			EXAMINER GHALI, ISIS A D	
			ART UNIT 1615	PAPER NUMBER
			MAIL DATE 07/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,898	Applicant(s) OPHEIM, JOAR	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14, 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14, 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicant's request for RCE, amendment and declaration, all filed 06/11/2007.

Claims 10-13 have been previously canceled, and claims 14 and 15 are currently added.

Claims 1-9, 14 and 15 are pending and included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/11/2007 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment has introduced new matter. Claim 1 is amended to recite 0.1 to 1.5% flavoring agent, and claim 3 is amended to recite 0.2 to 1.5% flavoring agent, and applicants are referring to pages 5-7 for support. With careful review to the specification, nowhere in the specification applicant has disclosed the flavoring is present at a concentration as instantly claimed. In page 3, lines 15-16, and page 6, lines 17 and 18, applicant disclosed that the "about 1 part by weight of the water soluble flavoring". In page 5, lines 23-25, applicant disclosed "0.5% of specific flavoring agent Firmenich #52311A", and not for any flavoring agent in general. In the paragraph bridging page 6 and 7, applicant disclosed "flavoring agent of 0.25 to 0.5% when Omega 3 is present in 80%". Therefore, applicant has no support for the claimed amount. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-9, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lachman et al. in combination with US 5,955,102 ('102) and US 5,718,323 ('323).

Lachman teaches a capsule shell comprising gelatin, plasticizer, water and flavor. The amount of plasticizer is calculated to be 40-60% and chosen according to the end use of the capsule and the effect of capsulated material on the shell. The amount of water is calculated to be 70-130% but water is lost during drying process. The flavor is present in a concentration of 0.1% to impart the desirable taste in chewable capsule (page 407, right column).

Lachman does not teach the claimed amount of the water and plasticizer, or fish oil as a dietary supplement.

However, Lachman suggested that plasticizer is chosen according to the end use of the capsule and the effect of capsulated material on the shell, and this teaching would have motivated one having ordinary skill in the art to adjust the amount of plasticizer according to the intended use and encapsulated material.

Additionally, Lachman teaches that the water is lost during drying process, i.e. the amount is expected to be radically reduced below 70%. Note that applicant discloses in page 6 of the specification, lines 1-2, that the amount of water present in

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the shell is 10-45%, and that amount is reduced to 8+/-2% after drying of the capsule.

The reference does not disclose if the amount before drying or after drying.

In any event, the amount of water and plasticizer do not impart patentability to the claims, absent evidence to the contrary.

Fish oil is well known dietary supplement, and also known to be provided in a gelatin capsules combined with flavoring agents.

US '102 teaches fish oil is preferably provided in a gelatin capsule (abstract; col.2, lines 31-36).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide shell of gelatin capsule as disclosed by Lachman that comprises gelatin, softener, water and small amount of flavor and use the capsule to deliver fish oil disclosed by US '102, motivated by the teaching of US '102 that the gelatin capsules are the preferred delivery method for the fish oil, with reasonable expectation of having a gelatin capsule comprising shell containing 1% of flavoring agent to impart the desired taste as disclosed by Lachman to deliver fish oil to the patient in need of such a nutrient with great success.

The combination of Lachman and US '102 does not explicitly teach water-soluble fruit flavors.

US '323 teaches soft gelatin capsule shell comprising flavoring agent selected from essential oils and fruit flavor or combinations thereof (col.5, lines 43-49). Examples C9 and C10 showed lemon flavor. Fruit flavors are expected to be water-soluble since compounds and their properties are inseparable.

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Therefore, the prior art recognized gelatin capsules with flavored shell, and also recognized the equivalency as well as the combination of essential oil flavors and fruit flavors.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide gelatin capsule to deliver fish oil comprising shell containing 1% of flavoring agent including essential oil to impart the desired taste as disclosed by the combined teaching of Lachman and US '102, and further add fruit flavor or replace the essential oil with the fruit flavor, especially lemon flavor, as disclosed by US '323, motivated by the desire of US '323 to flavor the shell of gelatin capsule with essential oil or fruit flavors, or their combination, with lemon flavor exemplified as a preferred flavor, with reasonable expectation of having gelatin capsule to deliver fish oil comprising shell containing 1% of fruit flavor, and specially lemon flavor, to impart palatable taste to unpleasant fish oil content of the capsule to successfully improve patient compliance.

Response to Arguments

6. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

7. The declaration under 37 CFR 1.132 filed 06/11/2007 is insufficient to overcome the rejection of claims 1-9 based upon U.S.C. 103 (a) as set forth in the last Office

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action because: there was no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. The scope of the claims is broad covering all flavors in amounts of 0.1% to 1.5%, while the declaration is limited only to one flavor, lemon flavor, at specific concentration of 1.0% in the shell and 1.0% in the content of the capsule. The species of the flavoring agent in specific concentration in the shell composition and specific amount in the content of the capsule of the declaration does not support the generic concept of the claims. There is no comparative data between the claimed amount of the flavor with amounts outside the upper and the lower ends of the claimed range. The declaration includes statements which amount to an affirmation that the claimed subject matter functions as it was intended to function. This is not relevant to the issue of nonobviousness of the claimed subject matter and provides no objective evidence thereof. See MPEP § 716.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis A Ghali
Primary Examiner
Art Unit 1615

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ISIS GHALI
PRIMARY EXAMINER